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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/643,743 | 08/19/2003 | Real Lemieux | 701826-054340 | 4127 |
| 50828 | 7590 | 11/13/2007 | EXAMINER | |
| DAVID S. RESNICK | | | SCHWADRON, RONALD B | |
| 100 SUMMER STREET | | | | |
| NIXON PEABODY LLP | | | ART UNIT | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|---|---------------------------------------|--|
| Office Action Summary | Application No. 10/643,743 | Applicant(s) LEMIEUX ET AL. | |
| | Examiner Ron Schwadron, Ph.D. | Art Unit 1644 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 1-8, 11, 12, 14-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 9, 10 and 13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/07 has been entered.

2. Claims 9,10,13 are under consideration.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The rejection of claims 9,10,13 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons elaborated in the previous Office Action is withdrawn in view of the amended claims.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 9,10,13 are rejected under 35 U.S.C. 102(b) as being anticipated by Bourel et al. (EP 1059088 A1) as evidenced by Bruley-Rosset et al.

Bourel et al. disclose purified autoantibodies isolated from IVIg, wherein said autoantibodies bind DNP-Lysine (aka DNP-haptene) or IgG (see abstract, claims 1-3,9 [0010], [0001], [0014]). Bourel et al. disclose a composition of said antibodies and a pharmaceutically acceptable carrier (see [0070]). It is an inherent property of said antibodies that said antibodies bind cytokines (aka serum proteins, see Bruley-Rosset

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et al., page 1017, second column, last paragraph) or IgG (serum protein). The functional properties of said antibodies recited in the claims are an inherent property of autoantibodies which bind soluble human serum proteins. Said antibodies are capable of forming autoimmune complexes because they are antibodies which bind soluble proteins present in human serum. Said autoantibodies have the property of claim 10 because they are the same type of autoantibodies as disclosed in the specification (polyclonal antibodies which bind soluble human serum proteins).

Regarding applicants comments, the prior art anticipates the claimed inventions as per above. Applicants comments and the Lemieux declaration address limitations not currently recited in the claims. The Lemieux declaration addresses *antibodies made by a particular method disclosed* in the specification wherein said method is not recited in the claims under consideration. Furthermore, the differences alluded to in the Lemieux declaration address *limitations currently not recited in the claims*. Claim 9 currently recites that the autoantibodies are isolated from therapeutic IVIg (as is the prior art antibodies) and are capable of forming autoimmune complexes in human serum (as are the prior art antibodies). Applicants arguments involve limitations not currently recited in the claims. Similarly, the prior art has the property of claim 10 for the reasons elaborated in the instant rejection. The Lemieux declaration addresses limitations that are not currently in the claims under consideration. It also does not address the anti IgG autoantibodies that are taught in the prior art and no longer excluded from the claimed invention as per the amended claim 9. Furthermore, according to Bruley-Rosset et al., anti-DNP autoantibodies isolated from IVIG actually have a higher degree of anticytokine reactivity than IVIG (see page 1017, second column, last paragraph). In addition, regarding Figure 1 in the Lemieux declaration, Bruley-Rosset et al. actually disclose strong binding of anti-DNP autoantibodies isolated from IVIG to actin (see Table 1).

7. No claim is allowed.

8. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the

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application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Ron Schwadron, Ph.D.

Primary Examiner

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